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| **Study Stage:** Start-up |



**Purpose:** The Site Initiation Meeting (SIM) Agenda serves to organize the meeting and should be used as a guide to describe the content to be covered during the SIM in order to ensure the site is prepared for the proper conduct of the study.

If it is an externally sponsored study, the sponsor will conduct the Site Initiation Meeting, calling it a Site Initiation Visit (SIV), a standard industry term for this meeting. The sponsor will provide their own agenda for the visit, however, you can use this as a reference for topics typically covered in this meeting.

The meeting should be held prior to the initiation of any study activity with participants and should include all study team members who have direct and/or indirect impact on running the clinical trial. The meeting should train staff on the protocol and study related processes; confirm site readiness for study implementation; and identify any additional requirements that must be satisfied prior to site activation and recruitment. It is preferable to verify procedural feasibility before the site initiation meeting, but the site initiation meeting is a critical opportunity for the entire team to identify challenges and verify feasibility to properly implement the study protocol.

**Useful to:** Investigators, Project Managers, Research Coordinators, and Monitors

**Instructions:**

* Define who is responsible for customizing the agenda, leading the meeting, presenting each topic and ensuring that all relevant parties are informed of the meeting date and time well in advance.
* Customize the list of topics, order of presentation, and duration of each discussion item to the specific requirements of the study. Include the name of each individual who will be the owner/presenter of each item.
* This template is designed for drug studies. For studies of devices and biologics it will require adaptation.

**Best Practice Recommendation:**

* Coordinate the SIM to include the PI and other key study team members including co-investigator(s), study manager(s), study coordinator(s), research nurse(s), data manager(s), pharmacist(s), research lab personnel and all team members listed on the Delegation of Authority Log (DOA.. All study team members should be asked to attend the SIM, but it is essential that the PI attends. If a study team member does not attend the SIM, they should document how and when they received those components of the SIM training that relate to their trial responsibilities.
* The SIM should generally be held after the study has IRB approval and the clinical trial agreement (including the budget) has been finalized. In addition, teams may also wait until the RP has received the drug products or devices (if applicable).
* It is recommended that review of roles and responsibilities according to the delegation of authority log occur during each meeting topic.
* Questions should be addressed topic by topic rather than at the end of the meeting.
* Those in attendance should sign a SIM Log of Attendance that includes affiliations, names, study role, and job title.
* Outstanding essential documents should be completed prior to or collected during the meeting.
* For very specific training that occurs outside of the site initiation visit document in a separate log.

**Template History:**

**Reference(s):**

**21 CFR 312.50**: General responsibilities of sponsors.

[**http://tinyurl.com/gwmt9kj**](http://tinyurl.com/gwmt9kj)

**21 CFR 312.60**: General responsibilities of investigators.[**http://tinyurl.com/h3fzdls**](http://tinyurl.com/h3fzdls)

**Last updated:** 6/07/2022

**Version:** 2.1

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| **Study Name:**  | **IRB HUM #:**  |
| **Principal Investigator:**  | **Date:**  |
| **Participants Attended:** |

**Agenda**

(This template is designed for drug studies. Adapt for studies of devices and biologics.)

| **Topic**  | **Presenter** | **Scheduled Time**  |
| --- | --- | --- |
| 1. Welcome, Introductions/Roles and Responsibilities

 (Refer to the Delegation of Authority Log)1. Investigator
2. Study Team Members
 |  | e.g., 9am-11 pm |
| 1. Protocol Overview
2. Study objectives
3. Enrollment goals
	* 1. Recruitment plans
		2. Screening and enrollment procedures
4. Informed consent process discussion
5. Inclusion/exclusion criteria
6. Study visit schedule/schedule of events
7. Study procedures
8. Prohibited and concomitant medications
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| 1. General Study Procedures (SOPs and MOPs if applicable)
2. ICH-GCP (usually for drug studies)
3. Participant registration process
4. Review participant study activity to identify processes and verify feasibility
5. Study supplies
6. Discussion of necessary updates
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| 1. Protocol Specific Training (if applicable)
	1. Vendors (Randomization system; Data Collection, Imaging Laboratory, etc.)
	2. Shipment of biological samples
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| 1. Safety: Definitions, Collection and Reporting
2. Adverse events (AEs)
3. Serious adverse events (SAEs)
4. Unanticipated problems
5. Dose modification
6. Withdrawal/Discontinuation and retreatment
7. Process for submitting queries
8. Medical monitor (if applicable)
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| 1. Investigational Product
2. Description of product
3. Review of Investigator Brochure (IB) or Package Insert (if applicable)
4. Storage conditions
5. Security and access (if applicable)
6. Dosing instructions
7. Dispensing
8. Documentation
9. Accountability
10. Return/destruction procedure
11. Unblinding procedures (if applicable)
12. U-M Research Pharmacy procedures (if applicable)
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| 1. Data Collection/Source Documentation
2. Paper or electronic data capture (EDC) CRF discussion
3. Storage of paper documents (if applicable)
4. Storage of electronic documents (secure server and backup, (21 CFR part 11) if applicable)
5. Source documents
6. Definition of
7. Retention of
8. Database training (if applicable)
9. Data entry process (include who is responsible for entering data and timeframes)
10. Coding process for medical terms (if applicable) Management of vendor data, core labs, etc.
11. Query process
12. Data security controls/Data Transfers/ PHI
13. Record retention
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| 1. Data Analysis
2. Data Safety Monitoring
3. FDA reporting
4. Data required for planned publications
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| 1. Specimen Processing
2. Collection
3. Lab requisition retention
4. Specimen storage plan
5. Shipping
6. Management of lab results/reference ranges
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| 1. Clinical Monitoring
2. Contacts
3. Responsibilities
4. Frequency
5. Close out procedures
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| 1. Reporting expectations and responsibilities
2. FDA annual and safety reports (if applicable)
3. DSMB (if applicable)
4. Clinicaltrials.gov
5. IRB
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| 1. Regulatory Binder and Essential Documents Review
2. 1572, 1571, Form 1195 (as applicable)
3. IRB approval documents: protocol, patient handouts including study surveys, recruitment materials, consent documents
4. CVs for study team members
5. Medical licenses for PI and Co-I’s
6. Financial disclosure forms
7. Delegation of Authority Log
8. Protocol Training Log
9. ICH-GCP training (CITI or other)
10. Human subjects training and responsible conduct of research and scholarship (RCRS) PEERS training
11. Monitoring Visit Log
12. Document updates
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| 1. Study Communications, Team Meetings, and Logistics
2. Frequency
3. Topics
4. Personnel
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| 1. Closing
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This template may be altered to meet study specific requirements; update versions as needed

Last Updated: MM/DD/YYYY

Version: Page:

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| **Attendance Log – Site Initiation Meeting** |
| **Study Name:**  | **IRB HUM #:** | **Site Name:** |
| **Principal Investigator:**  | **Date:**  |

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| --- | --- | --- | --- |
| **Name** | **Department** | **Study Role** | **Signature** |
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